Veklury® remdesivir 100 MG FOR INJECTION

LEADING THE WAY

What was the impact of VEKLURY use on hospital readmissions?

Learn about a retrospective analysis of real-world data

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg), who are:

- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

IMPORTANT SAFETY INFORMATION

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

Please see additional Important Safety Information throughout and full Prescribing Information here or attached.

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VEKLURY shortened recovery time in patients hospitalized with COVID-19[1,2]

5 DAYS SHORTER RECOVERY TIME WITH VEKLURY

In the ACTT-1 study,[1]

Median 10 days to recovery with VEKLURY vs 15 days with placebo; recovery rate ratio: 1.29 (95% CI, 1.12 to 1.49), $P < 0.001$

- The primary endpoint was time to recovery within 29 days after randomization based on an 8-point ordinal scale

Adverse reaction frequency was comparable between VEKLURY and placebo[1]

- All adverse reactions (ARs), Grades ≥3: 41 (8%) with VEKLURY vs 46 (9%) with placebo; serious ARs: 2 (0.4%)* vs 3 (0.6%); ARs leading to treatment discontinuation: 11 (2%)† vs 15 (3%)

Study design: ACTT-1 was a randomized, double-blind, placebo-controlled, phase 3 clinical trial in hospitalized adult patients with confirmed SARS-CoV-2 infection and mild, moderate, or severe COVID-19, who received VEKLURY (n=541) or placebo (n=521) for up to 10 days. Recovery was defined as patients who were no longer hospitalized or hospitalized but no longer required ongoing medical care for COVID-19.[1]

*Seizure (n=1), infusion-related reaction (n=1).
†Seizure (n=1), infusion-related reaction (n=1), transaminases increased (n=3), ALT increased and AST increased (n=1), GFR decreased (n=2), acute kidney injury (n=3).

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

- **Hypersensitivity, including infusion-related and anaphylactic reactions:** Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time of up to 120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).
- **Increased risk of transaminase elevations:** Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- **Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine:** Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments, demonstrating potential antagonism, which may lead to a decrease in the antiviral activity of VEKLURY.

Adverse reactions

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

Dosage and administration

— Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

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Real-World Study

Patients treated with VEKLURY were significantly less likely to be readmitted across variant periods[3]

Study overview[1]

A large, real-world, retrospective cohort study examined 30-day, all-cause readmission after COVID-19 hospitalization in adult patients (≥18 years of age) who were treated with VEKLURY vs those not treated with VEKLURY across variant periods pre-Delta (5/2020–4/2021), Delta (5/2021–11/2021), and Omicron (12/2021–4/2022).

The **primary endpoint** was 30-day, all-cause readmission to the same hospital after being discharged alive from the index COVID-19 hospitalization.*

- Data were examined using multivariate logistic regression. The model adjusted for age, corticosteroid use, variant period, Charlson Comorbidity Index (CCI), maximum oxygenation requirements, and ICU admission during COVID-19 hospitalization
- **This study was sponsored by Gilead Sciences, Inc.**

Study limitations

- Patients readmitted to a different hospital were not accounted for
- Since the model adjusted for multiple variables, patients were not matched
- Patients received at least 1 dose of VEKLURY; model did not account for the number of VEKLURY doses administered†
- Real-world studies should be interpreted based on the type and size of the source datasets and the methodologies used to mitigate potential confounding or bias. Real-world data should be considered in the context of all available data. Results may differ between studies

Data source

PINC AI™ Healthcare Database: This US hospital–based, service-level, all-payer (commercial, Medicare, Medicaid, others) database **covered approximately 25% of all US hospitalizations from 48 states**.

See the data on the following pages ❯

*Index COVID-19 hospitalization was defined as the first admission to the hospital between May 1, 2020, and April 30, 2022, with a primary discharge diagnosis of COVID-19.
†Refer to the Dosing and Administration section of the full Prescribing Information for dosage recommendations.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Treatment duration:**
  - For patients who **are hospitalized**, VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
  - For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days.
  - For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.

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Real-World Study

Patients treated with VEKLURY were significantly less likely to be readmitted across variant periods[3] (cont'd)

Study population

- **440,601 patients from 852 hospitals** with a primary diagnosis of COVID-19 that were discharged alive
- **248,785 VEKLURY patients** were compared to **191,816 non-VEKLURY** patients

The patient population included a broad range of:

- Comorbidities
- Supplemental oxygen requirements
- Ages
- Concomitant medications used*

POPULATION CHARACTERISTICS

Compared to nonreadmitted patients, readmitted patients:

- **Were older:** median 71 years vs 63 years
- **Had more comorbidities:** CCI ≥4: 36% vs 16%
- **Were more likely to have NSOc:** 42% vs 39%
- **Were less likely to be:**
  - On low-flow oxygen: 40% vs 42%
  - Treated with any VEKLURY: 48% vs 57%
- **Had an equal proportion of:**
  - High-flow oxygen/NIV: 16% vs 16%
  - IMV/ECMO: 3% vs 3%
- **Had comparable length of stay:** median 5 days vs 5 days

Compared to non-VEKLURY patients, VEKLURY patients:

- **Were younger:** median 62 years vs 64 years
- **Were less likely to have NSOc:** 30% vs 52%
- **Were more likely to be on:**
  - Low-flow oxygen: 46% vs 36%
  - High-flow oxygen/NIV: 20% vs 10%
  - IMV/ECMO: 4% vs 2%

*Other treatments administered at baseline for patients (across both study arms) included corticosteroids, tocilizumab, and baricitinib as well as combinations of the aforementioned treatments.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Treatment duration** (cont'd)**:**
  - For patients who are **not hospitalized**, diagnosed with mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset for outpatient use.
- **Testing prior to and during treatment:** Perform hepatic laboratory and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** No dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment, including patients on dialysis. VEKLURY may be administered without regard to the timing of dialysis.

ECMO=extracorporeal membrane oxygenation; IMV=invasive mechanical ventilation; NIV=noninvasive ventilation; NSOc=no supplemental oxygen charges.

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Real-World Study

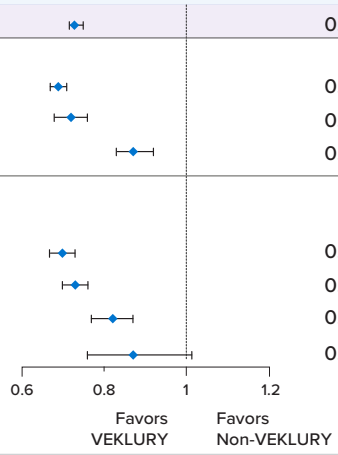
Patients treated with VEKLURY had significantly reduced readmission rates across variant periods[3]

27% Reduction of 30-day, all-cause readmission was observed with VEKLURY

In the overall cohort, patients treated with VEKLURY were **27% less likely to be readmitted** within 30 days; aOR: 0.73 (95% CI, 0.72 to 0.75), *P* < 0.0001.

30-day, all-cause reduction in readmission was significant across variant periods and by maximum oxygenation in index hospitalization (May 2020 through April 2022)

	Readmitted patients/Total number of patients		Likelihood of 30-day readmission aOR with 95% CI	aOR (95% CI)	*P* value
	VEKLURY	Non-VEKLURY			
Overall cohort	15,780/248,785	17,437/191,816		0.73 (0.72 to 0.75)	<0.0001
Variant period					
Pre-Delta	7,766/122,560	10,176/109,348		0.69 (0.67 to 0.71)	<0.0001
Delta	4,256/83,178	3,466/44,215		0.72 (0.68 to 0.76)	<0.0001
Omicron	3,758/43,047	3,795/38,253		0.87 (0.83 to 0.92)	<0.0001
Maximum oxygenation in index hospitalization					
No supplemental oxygen	4,806/73,859	9,055/99,030		0.70 (0.67 to 0.73)	<0.0001
Low-flow oxygen	7,025/115,923	6,181/68,389		0.73 (0.70 to 0.76)	<0.0001
High-flow oxygen/NIV	3,379/50,029	1,834/19,815		0.82 (0.77 to 0.87)	<0.0001
IMV/ECMO	570/8,974	367/4,582		0.87 (0.76 to 1.01)	0.0613



- **This statistically significant reduction was observed for all supplemental oxygen levels, except for patients in the IMV/ECMO group, which did not meet statistical significance due to low sample size in this group**
- The lower readmission rate for VEKLURY patients was observed despite this group having a higher supplemental oxygen requirement during their index COVID-19 hospitalization, as compared to the non-VEKLURY group

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** A pregnancy registry has been established for VEKLURY. Available clinical trial data for VEKLURY in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following second- and third-trimester exposure. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester. Maternal and fetal risks are associated with untreated COVID-19 in pregnancy.
- **Lactation:** VEKLURY can pass into breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEKLURY and any potential adverse effects on the breastfed child from VEKLURY or from an underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

aOR=adjusted odds ratio.

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Start VEKLURY right away in your patients hospitalized with COVID-19

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References: 1. VEKLURY. Prescribing Information. Gilead Sciences, Inc.; 2023. **2.** Beigel JH, Tomashek KM, Dodd LE, et al; ACTT-1 Study Group Members. Remdesivir for the treatment of COVID-19—final report. *N Engl J Med*. 2020;383(19):1813-1826. doi:10.1056/NEJMoa2007764 **3.** Mozaffari E, Chandak A, Gottlieb RL, et al. Remdesivir is associated with reduced readmission after COVID-19 hospitalization. Poster presented at: 30th Conference on Retroviruses and Opportunistic Infections; February 19-22, 2023; Seattle, WA; poster 558. Accessed May 31, 2023. https://www.croiconference.org/wp-content/uploads/sites/2/posters/2023/RDV_Readmission_analysis_CROI_poster_Feb14_for_upload-133208797557610573.pdf

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